MANITOBA
PATIENT SERVICE CENTRE STANDARDS

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INTRODUCTION

These Standards are derived from Z316.7-12 and are approved by the Council of the College of Physicians and Surgeons of Manitoba. These standards will be used to assess the safety and quality of Patient Service Centres in Manitoba.

1. Patient Safety
2. Facility Conditions
3. Equipment
4. Personnel
5. Infection Prevention
6. Primary Sample Collection
7. Identification of Samples
8. Sample Integrity
9. Transport of Samples

In addition to these Patient Service Centre specific standards, the following Manitoba Laboratory Standards apply: Quality Management Program, Manuals, Safety and Equipment apply to all laboratory facilities.

1.0 PATIENT SAFETY AND QUALITY OF CARE

1.1 Patient Communication

1.1.1 Personnel must obtain consent before proceeding with the collection of specimens.

1.2 Privacy and Confidentiality

1.2.1 Personal patient information must be kept private and confidential.

1.3 Patient Physical Safety Considerations

1.3.1 Policies and procedures must be in place to respond to emergencies in case of patient illness or injury.
1.3.2 Facilities must have policies that:

- 1.3.2.1 define blood sample volumes required for the performance of each test, including tests on neonates, children, the very sick, and the elderly.
- 1.3.2.2 limit the number of attempts at blood sample collection to minimize patient inconvenience and/or harm.
- 1.3.2.3 notify the ordering physician about any failure to collect a blood sample.

2.0 FACILITY CONDITIONS

2.1 Samples must be safeguarded from unauthorized access.
2.2 Surfaces that are visibly soiled must be disinfected.
2.3 Precautionary measures for dealing with violent or uncooperative patients must be in place.
2.4 Primary sample collection must be performed in an area that:

- 2.4.1 provides sufficient privacy to ensure that patients can speak confidentially.
- 2.4.2 provides personal privacy for the patient during primary sample collection, e.g. during a blood draw or collection of a urine sample, and when removal of clothing is necessary.
- 2.4.3 protects confidential information on documents and in electronic systems.

3.0 EQUIPMENT AND SUPPLIES

3.1 Equipment and supplies must be available in sufficient quantities and suitable for their intended use in sample collection, stabilization, transport, and storage processes.
3.2 Equipment and supplies must be clean and well maintained. Supplies must be kept under controlled conditions during transport and storage.

3.1 Supplies

3.1.1 Supplies must be used before their expiry date.
3.1.2 Sterile single-use supplies must be used whenever possible in primary sample collection.
3.1.3 Trays or carts used to hold supplies must be made of materials that can be cleaned and disinfected.
3.1.4 Tourniquets must be latex free or be applied on top of clothing.

3.2 Equipment

3.2.1 Equipment used in primary sample collection, beds, chairs, and countertops must be made of materials that can be easily cleaned and disinfected when soiled.
3.2.2 Records must be maintained for, the following:

- 3.2.2.1 identification of the equipment, i.e. its type and serial number or other unique identification.
- 3.2.2.2 the manufacturer's name, contact person, and telephone number.
- 3.2.2.3 the date of receipt and the date the equipment was put into service.
- 3.2.2.4 the equipment's condition when received, e.g. new, used, or reconditioned.
- 3.2.2.5 the equipment manufacturer's instructions.
- 3.2.2.6 records of maintenance and service carried out and planned.
- 3.2.2.7 records of equipment damage, malfunctions, modifications, and repairs.
- 3.2.2.8 records must be maintained and readily available throughout the life of the equipment, plus 2 years.

3.2.3 Equipment must be operated by authorized personnel only.
3.2.4 Equipment must be maintained in a safe working condition.

3.2.5 When equipment is found to be defective, it must be taken out of service, clearly labelled, and appropriately stored until it has been repaired and shown, by calibration or verification, to meet specified acceptance criteria. The impact of the defect shall be evaluated. The facility shall take reasonable measures to decontaminate equipment prior to servicing, repair, or decommissioning.

3.2.6 A list of the measures taken to reduce contamination must be provided to the personnel using the equipment.

3.2.7 Computer programs must be adequately protected to prevent unauthorized or inadvertent access, alteration, or destruction.

3.3 Personal Protective Equipment

3.3.1 Personal protective equipment (PPE) must be available for persons collecting and handling samples. Hypoallergenic PPE, e.g. non-latex gloves, must be available when necessary.

4.0 PERSONNEL

4.1 Facility must have policies, and job descriptions that define the qualifications and duties of all personnel.

4.2 Personnel must have quality assurance and quality management training applicable to the services offered by the facility.

4.3 The facility must have an orientation process for newly hired personnel. Training must include, but not be limited to, the following:

- 4.3.1 policies and procedures for:
  - 4.3.1.1 accurate patient and sample identification.
  - 4.3.1.2 proper collection techniques for the specimen types likely to be encountered.
  - 4.3.1.3 sample storage and handling requirements.
  - 4.3.1.4 reporting documentation and analysis of adverse events and other incidents.
  - 4.3.1.5 prevention or containment of the effects of adverse events, e.g. first aid training.
  - 4.3.1.6 use of computers and other relevant information technology.
- 4.3.2 safety and infection control.
- 4.3.3 patient privacy and confidentiality of patient information.
- 4.3.4 WHMIS.
- 4.3.5 transportation of dangerous goods regulations (if applicable).

4.4 The competence of each person to perform assigned tasks must be assessed following training and periodically thereafter. Retraining and reassessment must occur when necessary.

4.5 Confidentiality of patient information must be maintained by all personnel.

5.0 INFECTION PREVENTION AND CONTROL

5.1 Hand hygiene, must at a minimum, be performed before and after each patient contact and between different patients as well as after glove removal. In circumstances where hands look or feel dirty, they must be washed with soap and water.

5.2 When performing pre-examination activities, personal protective equipment that is appropriate to the task must be worn, and such equipment must be properly fitted, e.g. gloves, gowns, and masks. Gloves must be changed between each primary sample collection.

5.3 Single-use equipment must be disposed of appropriately after each collection in accordance with relevant regulations.

5.4 Routine patient care equipment, e.g. tourniquets must be cleaned or disposed of between patients.

6.0 PRIMARY SAMPLE COLLECTION

6.1 General

6.1.1 Instructions for the proper collection and handling of primary samples must be made available to personnel responsible for primary sample collection.

6.2 Primary Sample Collection Manual

6.2.1 The primary sample collection manual must include the following:

6.2.1.1 copies of or references to:

1. lists of the laboratory examinations offered.
2. consent forms, when applicable.
3. the information and instructions provided to patients in relation to their own preparation before primary sample collection.
4. information for users of laboratory services on medical indications and appropriate selection of available procedures.
5. sample acceptance and rejection criteria.
6. safety precautions for toxic or hazardous materials that are provided for self collection, e.g. 24 h urine containers to which preservatives have been added.
7. labelling and packaging of self-collected primary samples.
8. any additional special handling requirements between the time of collection and the time that the sample is received by the laboratory.
9. a list of pre-examination factors that can affect test results.
10. statements of primary sample collection or testing priorities and allowable turnaround times.
11. information on hours of operation of the primary sample collection service or the testing laboratory and telephone numbers.
12. sample receiving or drop-off locations.

6.2.1.2 procedures or instructions for:

1. completion of the paper or electronic request form.
2. preparation of the patient.
3. selection of appropriate site for primary sample collection, and selection of equipment (as applicable) to optimize the integrity of the sample and the well-being of the patient.
4. handling patients with communication challenges.
5. positive identification and labelling, using two unique identifiers (patient first name, patient last name, and unique identification number).
6. the type and amount of the primary sample to be collected, including, the correct volume of primary sample for the volume of additive or preservative in a tube or container.
7. primary sample collection, e.g. collection of blood, urine, and other bodily fluids, with descriptions of the primary sample containers and any necessary additives.
8. timed urine or blood collections.
9. labelling of samples.
10. recording the date and time of collection as well as the identity of the person collecting the primary sample.
11. safe disposal of materials used in the collection.
12. storage of examined samples.
13. additional examinations, including time limits for requesting such examinations.

6.3 Sample Requests

6.3.1 The request form must contain information sufficient to identify the patient and the authorized requester, as well as pertinent clinical data. The request form must allow space for the inclusion of, but not be limited to, the following:

6.3.1.1 unique identification of the patient, including the following:

1. the first and last name of the patient.
2. the unique patient identifier, e.g. PHIN.
3. the date of birth and gender of the patient.

6.3.1.2 patient contact information.

6.3.1.3 the name or other unique identifier of the physician and the emergency contact information of the healthcare professional for reporting critical results.

6.3.1.4 the type of primary sample, e.g. throat swab and the anatomic site of origin, where appropriate, e.g. abdominal wound, artery, or vein.
6.3.1.5 the examinations requested.
6.3.1.6 clinical information relevant to the patient.
6.3.1.7 the date the test request form was completed.
6.3.1.8 the date and time of primary sample collection and the identity of the collector.
6.3.1.9 the date and time of receipt of the sample by the laboratory.

6.3.2 The facility must have a written policy concerning verbal requests for examinations.

6.4 Verification of the Patient's Identification

6.4.1 The facility must have operating procedures for the verification of patient identification prior to primary sample collection. The procedures must include the following:

6.4.1.1 unique patient identifiers.

1. routine primary sample collection.
2. primary sample collection in emergencies (if applicable).

6.4.1.2 before initiating collection, patient identity must be verified by the person collecting the primary sample, using, at a minimum, two unique identifiers.
6.4.1.3 patients must be asked to state identifiers and the information provided must be compared to the information on the request for sample collection or test request form and any facility ID band the patient is wearing.
6.4.1.4 if a patient is unable to state the required identifiers:

1. the identity must be verified by a person who knows the patient, e.g. a relative or caregiver.
2. the name of the person who confirmed the patient's identity must be recorded.

6.5 Verification of the Sample Request Form

6.5.1 The sample request form must be reviewed for completeness.
6.5.2 Any discrepancy noted must be resolved by the person assigned to collect the primary sample before proceeding with collection.

6.6 Pre-examination Requirements

6.6.1 Clear and precise instructions must be given to the patient with regard to collection pre-examination requirements including:

6.6.1.1 fasting.
6.6.1.2 special diet.
6.6.1.3 medications that are not recommended to be taken prior to collection.
6.6.1.4 requirements for specific time of last dose of medication.
6.6.1.5 requirements for collecting the primary sample at a precise time.
6.6.1.6 instructions, if applicable, for self-collection by the patient, e.g. midstream urine collection and fecal collections.

6.6.2 The person collecting the primary sample (or accepting it in the case of a primary sample self-collected by the patient) must ensure all pre-examination requirements for the tests ordered have been met.
6.6.3 If the pre-examination instructions were not followed, collection must not proceed and the patient must be instructed to return at another time when the requirements have been met.
6.6.4 If pre-examination requirements have not been met, a note specifying which requirements have not been met must be added to the sample request and, if applicable, must be added to the report.

6.7 Special considerations when performing phlebotomy procedures

6.7.1 Venipuncture Procedures

6.7.1.1 Tourniquet application time must not exceed 1 min.
6.7.1.2 Patients must be instructed to avoid hand pumping before and during collection of the sample.
6.7.1.3 Tubes containing the appropriate additive must be selected for blood collection in accordance with the tests requested. The tubes must be:

1. filled to the volume specified by the manufacturer to ensure the optimal blood-to-anticoagulant ratio.
2. mixed in accordance with the manufacturer's instructions when blood samples are collected into a tube containing additives.

6.7.1.4 The current order of draw specified by the tube manufacturer must be followed when collecting multiple blood samples during a single venipuncture or capillary blood collection.

6.7.1.5 Strict aseptic technique must be used when collecting blood culture samples. Routine blood cultures involve paired aerobic/anaerobic blood culture bottles, which must be collected in accordance with the manufacturer's instructions.

6.7.1.6 Blood must not be collected from the arm on the side of a mastectomy. The patient's authorized healthcare provider must be consulted to determine suitable sites in the case of a patient who has undergone a bilateral mastectomy.

6.7.1.7 When sites are selected for venipuncture, areas exhibiting the following should be avoided:

1. edema.
2. Hematoma.
3. extensive scarring.
4. fresh tattoos.
5. burns.
6. damaged or occluded veins.
7. fistulas.

6.7.2 Adult Capillary Puncture

6.7.2.1 An appropriate puncture site must be selected, e.g. the middle or ring finger.

6.7.2.2 Capillary punctures must not be performed on fingers on the side of a mastectomy. Edematous, bruised, and previously punctured areas must be avoided.

6.7.2.3 The first drop of blood must be wiped away before proceeding with blood collection unless specifically indicated for the test.

6.7.3 Pediatric Phlebotomy

6.7.3.1 An appropriate collection technique. i.e. venipuncture or capillary must be selected for collecting blood samples from pediatric patients.

6.7.3.2 The person performing pediatric blood collection must follow established procedures for pediatric patients.

6.7.3.3 Low-volume tubes must be used when collecting blood samples from pediatric patients.

6.7.4 Pediatric Capillary Puncture

6.7.4.1 Appropriate puncture devices must be selected based on the weight of the patient or other criteria.

6.7.4.2 Puncture sites must be selected in accordance with the following considerations:

1. the lateral or medial plantar surface of the heel is commonly the site of choice for children under one year old or who have not begun to walk.
2. if a finger is used as the puncture site, the middle or ring finger is commonly the site of choice.
3. edematous, bruised, and previously punctured areas must be avoided.

6.7.4.3 The first drop of blood must be wiped away before proceeding with blood collection unless specifically contraindicated for the test.

6.8 Samples Collected for Biochemical, Hematological, Coagulation, or Transfusion Medicine

6.8.1 Primary samples collected for testing must be collected and handled in a way that maintains the integrity of the biochemical and/or cellular components to be tested.

6.8.2 Procedures and policies to ensure the respect of optimal environmental conditions and time limitations for the transport and storage of sample testing.

6.9 Post-Collection Care

6.9.1 Procedures must be in place to ensure that proper care and instructions are given to the patient following sample collection, e.g. providing adequate pressure on the puncture site following phlebotomy procedures.

7.0 IDENTIFICATION OF SAMPLES

7.1 Primary samples must be labelled immediately after the phlebotomy or other collection procedure and in the presence of the patient. For each sample, the laboratory must require the following data:

1. the first and last name of the patient.
2. the unique patient identifier; e.g. PHIN.
3. the date and time of collection.
4. the identity of the person who collected the primary sample.

8.0 SAMPLE INTEGRITY

8.1 Samples must be kept under conditions that will maintain their integrity until analytic testing can be performed as well as for a specified period of time after testing has occurred (for add-on testing).

8.2 The patient service centre must be aware of the criteria of acceptance or rejection of samples of the testing laboratory.

8.3 Facility sample rejection policies and procedures must take into account, but not be limited to, the following:

8.3.1 samples that are not properly identified.
8.3.2 an inappropriate collection container.
8.3.3 an insufficient or excessive amount of a sample.
8.3.4 inappropriate transport and storage of samples.
8.3.5 clotted samples in tubes with anticoagulant.
8.3.6 hemolyzed samples that meet the laboratory's criteria for rejection.
8.3.7 samples that present a safety risk to personnel, e.g. leaking sample or samples submitted in syringes with needles attached.

9.0 TRANSPORT OF SAMPLES

9.1 General

9.1.1 Samples must be transported in a way that ensures that the integrity of the samples and the safety of the carrier, the public, and the referral laboratory are maintained at all times.

9.1.2 The referral laboratory must ensure that instructions for proper packaging and transport of samples are readily available to the primary sample collection service or referring laboratory.

9.1.3 Samples transported within a healthcare facility must be transported safely using a robust or leak-proof container, e.g. a phlebotomy cart or a sealed plastic bag in order to contain the sample in case of spillage.

9.1.4 Each sample must be maintained apart from other samples to prevent contamination.

9.1.5 Samples must be transported in an upright position to prevent leakage, facilitate complete clot formation, and reduce agitation of the tube's contents (to reduce the potential for hemolysis).

9.1.6 To avoid contamination in case of leakage, sample requests and any other documentation must not be in direct contact with samples.

9.1.7 Samples must be transported in a manner that respects patient confidentiality.

9.1.8 To maintain sample integrity, the analyte stability period, optimal temperature, and other conditions required for a test to be performed must be observed during the transport of the sample to the referral laboratory. Delays and any deviations from the established environmental conditions must be noted on the test request, in the patient's record, and in the test report.